



Timing Of venous thromboembolism Prophylaxis for adult patients with Traumatic Brain Injury (TOP-TBI): a pragmatic, randomised trial

Summary of Participant Information Sheet

In this summary information sheet for the TOP-TBI trial, we use the term “you” referring to the trial participant. However, in cases where participants cannot read this document themselves, a friend/relative can read this summary on their behalf although the term “you” still refers to the participant and not the person reading this summary.

You are being invited to take part in the TOP-TBI research trial because you have suffered a traumatic brain injury (TBI). Suffering a TBI increases the chance of developing blood clots in the veins (VTEs) which complicate recovery, lead to long-term reduction to quality of life and can occasionally be fatal.

TBI patients are typically given blood thinning medications to reduce the chances of developing blood clots and to improve their long-term function outlook and quality of life. Some doctors start blood thinning medications within 72 hours from injury, but other doctors prefer to delay giving these drugs for 5 days or more or not give them at all as they are worried that the drugs may increase the risk of further bleed in the brain. However, several studies have shown that following TBI, giving blood thinning medication within 72 hours of injury does not increase the risk of further bleeding.

This study is designed to compare the timing of giving blood thinning medication following TBI and to guide the best practices in the future for starting blood thinning medication in order to reduce the rate of blood clots, without introducing complications from further bleeding. In this trial, we will be comparing the early initiation of blood thinning medications (within 72 hours from injury) to late initiation (deferred by a minimum of 120 hours from injury or not given at all if deemed clinically unnecessary by clinical team).

If you decide to participate, you will be randomly allocated (by a computer) to either the “Early group” starting blood thinning medication within 72 hours of injury or the “Late group” where medication will be deferred by at least 120 hours from injury or not given at all. The rest of your medical treatment and care will not change from usual

clinical practice and it is important to understand that the doctor treating you has no influence on whether you are allocated to the "Early" or "Late" group.

Participating in this trial is completely voluntary. If you are interested in participating, you will be given a more detailed Patient Information Sheet to read and will have the opportunity to discuss the details with the trial doctor and ask questions. If you decide to participate you will sign a consent form. You will be free to change your mind and leave the trial at any time and your future medical treatment and normal standard of care will not be affected in any way.

If you decide to participate, you will have some medical tests to establish if you are eligible to take part and if you are, you will be allocated to one of the two groups of the trial, the "Early" or the "Late" and will receive the medication via an injection into your skin or orally with a tablet while you are in the hospital. During the course of 1 year following your TBI we will contact you at 30 days to ask about the state of your health and you will also be asked to complete a short questionnaire pack which will be sent to you by post or email at 3 months, 6 months and 12 months, or it can be completed via the telephone.

There is no guarantee that you will benefit from taking part in this trial but the timing of starting the blood thinning medication following TBI may prevent you from developing a blood clot without introducing complications from further bleeding. If you take part in the trial you may be seen more often and feel more supported.

There are no additional disadvantages or risks involved in taking part in the trial as the medication to be used in the trial and the timings of giving the medication are routinely used by doctors to prevent blood clots following TBI.

As with any medication, there are possible side effects. The most frequently reported side effects of blood thinning medication are: Injection site reactions such as redness, irritation, and bruising; Heparin-induced thrombocytopenia (low platelet count); Bleeding. Other possible side effects could be headache, dizziness, sleep problems, high blood pressure, high potassium, mood changes, decreased bone mineral density; liver problems. However, your doctor will be monitoring you closely and if you suffer from any serious side effects the drug will be stopped immediately.

In order to conduct this trial, the study team will need to collect some personal information about you such as name, address, NHS number, Date of Birth and contact details in order to send the questionnaire pack. All information collected about you will be kept securely and strictly confidential and will only be accessed by authorised members of the trial team and UK regulatory agencies. Results of the trial will be anonymous and presented in a way that individual participants cannot be identified.

If at any time during the trial treatment you have any concerns or complaints about any aspect of the trial you should speak to the trial doctor and they will do their best to address these.

The TOP-TBI trial is a non-commercial trial funded by the National Institute for Health Research (NIHR) and has been reviewed by both a Research Ethics Committee (REC) and the Medicines and Healthcare Products Regulatory Agency (MHRA) to ensure the safety and wellbeing of participants.

For further information and for a more detailed Patient Information Sheet and Consent Form please contact:

(contact details of trial team)